## Remarks

Claims 1, 2, 4-8, 10-21, 23-26, 28-31, and 34-38 were pending in this application. By this amendment, claims 1, 7-8, 10-18, 24, and 34-38 are canceled. Claims 19-21, 26-26, and 28-31 have been withdrawn from consideration. New claims 39-51 are added herein. Claims 2, 4, 6, 19, and 23 are amended herein (of which, claim 19 is withdrawn).

Claims 2 and 4 are amended to place them in independent form. In addition, claims 2, 4, and 6 are amended to be directed to the elected sequence (SEQ ID NO: 15). Claims 6, 19, and 23 are amended to correct dependency. Support for new claims 39-42 can be found in the specification at least at page 15, lines 21-39. Support for new claim 43 can be found in the specification at least at page 12, line 27 through page 13, line 2 and at page 16, lines 14-37. Support for new claims 44-49 can be found in the specification at least at page 9, line 36 through page 10, line 21. Support for new claims 50-51 can be found in the specification at least at page 15, lines 21-39 and at page 16, lines 14-37.

Applicants thank the Examiner for acknowledging that the preliminary amendment submitted on April 29, 2005, has been entered. Applicants also thank the Examiner for acknowledging that the prior art does not teach or suggest an isolated and purified salivary *Lu. Longipalpis* polypeptide comprising the amino acid sequence SEQ ID NO: 15.

Applicants believe that no new matter has been added by these amendments. Applicants reserve the right to pursue the deleted and canceled subject matter in a related application. After entry of this amendment, claims 2, 4-6, 19-21, 23, 25, 26, 28-31, and 39-51 are pending (of which claims 19-21, 25-26, and 28-31 remain withdrawn). Reconsideration of the pending claims is respectfully requested.

*Restriction Requirement*

Applicants acknowledge that the elections of Group I (claims 1-6 and 23, in part; directed to a substantially purified salivary *Lu. longipalpis* polypeptide and a composition comprising said polypeptide) and SEQ ID NO: 15 are made final. The claims of Groups II-VIII are withdrawn or canceled.

*Information Disclosure Statement (IDS)*

Applicants thank the Examiner for reviewing and initialing the Information Disclosure Statements submitted on June 29, 2005 and June 29, 2006 (received by the United States Patent and Trademark Office on July 1, 2005 and July 3, 2006).

*Claim Objection*

Claim 4 is objected to for being dependent upon a rejected base claim. Solely to advance prosecution in this case, claim 4 is amended herein to be in independent form. Applicants submit that claim 4, and claims 5, 42, 44-51 that depend therefrom, are now in condition for allowance, which action is respectfully requested.

*Claim Rejections Under 35 U.S.C. §112, first paragraph (written description)*

Claims 2, 5, and 6 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking adequate written description in the specification. Specifically, the Office alleges that "only an isolated and substantially purified salivary *Lu. longipalpis* polypeptide comprising the amino acid sequence set forth as SEQ ID NO: 15 but not the full breath of the claim meets the written description provision of 35 U.S.C. §112, first paragraph" (Office action at page 4). Applicants traverse this rejection. Solely to advance prosecution in this case, claims 2 and 4 are amended to be directed to a substantially purified salivary *Lu. longipalpis* polypeptide comprising "an amino acid sequence at least 95% identical to an amino acid sequence set forth as SEQ ID NO: 15."

As established in *Ex parte Parks*, "adequate description under the first paragraph of 35 U.S.C. 112 does not require literal support for the claimed invention. . . . Rather, it is sufficient if the originally-filed disclosure would have conveyed to one having ordinary skill in the art that an appellant had possession of the concept of what is claimed" *Ex parte Parks,* 30 USPQ2d 1234, 1236-37 (B.P.A.I. 1993) (emphasis added). Moreover, the MPEP at §2163 states that "[w]hat is conventional or well known to one of skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.,* 802 F.2d at 1384,231 USPQ at 94. If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification,

then the adequate description requirement is met. See, e.g. *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson,* 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient")."

In the current instance, the original disclosure clearly conveys that Applicants had possession of the claimed invention, and certainly of the concept of what is currently claimed. Applicants had possession of the peptide sequence set forth in SEQ ID NO: 15. Applicants had also contemplated and provided explicit written description of polypeptides comprising at least 95% sequence identity to SEQ ID NO: 15 (specification, for example, at page 15, lines 5-39; page 23, lines 22-24), conservative variants of SEQ ID NO: 15 (for example, at page 7, line 33 through page 8, line 28), and immunogenic fragments comprising at least eight consecutive amino acids of SEQ ID NO: 15 (for example, at page 23, line 35 through page 24, line 2; page 50, lines 10-22).

Applicants also note that alignment methods are provided for identifying the claimed variants of SEQ ID NO: 15 (for example, at page 15, lines 5-39) and the specification describes that the claimed polypeptides can be purified and sequenced using standard techniques (for example, at page 14, lines 1-7; page 24, lines 22-25; page 45, line 36 through page 46, line 2). Methods are also provided for identifying sequence variants having the claimed activity (for example, Examples 4 and 5 at page 72, line 36 through page 74, line 24). Thus, the specification provides sufficient written description to convey to one of skill in the art that the inventors had possession of the claimed polypeptides at the time the application was filed.

The Office is reminded that the description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces. Guidelines for Examination of Patent Applications under the 35 U.S.C. § 112, ¶ 1, "Written Description" Requirement 66 Fed. Reg. 1099, 1106 (2001). Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that Applicants were in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. *Id*. Applicants submit that the knowledge and level of skill in the art would allow a person of

ordinary skill to envision the claimed sequences based on the teachings of the specification, the provision of SEQ ID NO: 15 itself, and its activity (producing an immune response to *Lu. longipalpis* in a subject). As claims 2, 5, and 6 are sufficiently described by the specification, Applicants request that the rejection under 35 U.S.C. §112, first paragraph, be withdrawn.

*Claim Rejections Under 35 U.S.C. §112, first paragraph (enablement)*

Claims 2, 5-6 and 23 are rejected under 35 U.S.C. §112, first paragraph, as allegedly the specification does not reasonably provide enablement for variants of SEQ ID NO: 15 and pharmaceutical compositions comprising substantially purified salivary *Lu. longipalpis* polypeptide. Applicants respectfully traverse this rejection.

The Office alleges that "[o]ne cannot extrapolate the teaching of the specification to the full enablement of the claims because the claims as written are drawn to undefined purified salivary gland polypeptide variant or polypeptide variants [of] SEQ ID NO: 15 (i.e., variants), and yet perform the contemplated function (inhibition of Leishmania) and neither the specification nor the art of record define these variants . . . the specification fails to teach variants of SEQ ID NO: 15 or pharmaceutical composition[s] comprising salivary polypeptide SEQ ID NO: 15" (Office action at page 5). The Office also alleges that "the specification provides no disclosure how to vaccinate human[s] against Leishmania (i.e. various species) using the claimed composition because it fails to provide guidance whether the claimed composition provides protection against species of *L. longipalpis* that transmit Leishmania" (Office action at page 7). Applicants disagree.

As discussed above, the specification provides explicit written description of polypeptides comprising at least 95% sequence identity to SEQ ID NO: 15, conservative variants of SEQ ID NO: 15, and immunogenic fragments comprising at least eight consecutive amino acids of SEQ ID NO: 15. In addition, the specification clearly describes pharmaceutical compositions comprising the claimed polypeptides (see, for example, the section entitled "Immunogenic Compositions, Vaccines, and Methods of Use" at page 49, line 37 through page 58, line 24). Furthermore, the Federal Circuit has repeatedly stated that enablement is not precluded by the necessity for some experimentation, so long as the experimentation is not

undue. *In re Wands* 8 USPQ2d 1400 (Fed. Cir. 1988). A considerable amount of experimentation is permissible, if it is **merely routine**, or if the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *Id.* Applicants submit that any experimentation would be routine and the present application provides the guidance necessary to carry out the claimed methods. For example, the specification teaches the following:

> (i) methods of obtaining the disclosed polypeptides (including variants) either by isolation and purification, by recombinant methods, or by chemical synthesis (page 11, line29 through page12, line 26; page 14, lines 1-16; page 43, line 5 through page 46, line 2; page 65, line 16 through page 69, line 27);
> (ii) methods of testing the antigenic and/or immunogenic properties of the disclosed isolated polypeptides by vaccinating mice or dogs and analyzing the subsequent inflammatory and immune responses (page 72, line 37 through page 74, line 24);
> (iii) methods of preparing pharmaceutical compositions directed against Leishmaniasis (page 12, line 27 through page 13, line 2; page 49, line 37 through page 58, line 24); and
> (iv) methods of immunization against Leishmaniasis (page 58, line 26 through page 62, line8).

Applicants note that the specification discloses the synthesis, testing, and use of *35 different polypeptides* (not simply SEQ ID NO: 15) and that the methods taught in the specification can be used to synthesize, test, and use large numbers of polypeptides. Thus, as evidenced by the teachings of the specification and the knowledge of one of skill in the art at the time the application was filed, it would be simply a matter of **routine** to (i) make the genus of claimed *Lu. longipalpis* polypeptides; (ii) test these polypeptides for their ability to protect a subject against species of *Lu. longipalpis* that transmit *Leishmania*; and (iii) use them to prevent, treat, or cure infection caused by *Leishmania*. Applicants further submit that, contrary to the assertion of the Office action (page 7), such experimentation would not be undue. In light of the above discussion, Applicants submit that the claims, as amended, are fully enabled by the specification and respectfully request that the rejection of claims 2, 5-6, and 23 under 35 U.S.C. §112, first paragraph, be withdrawn.

*Claim Rejections Under 35 U.S.C. §102(b)*

Charlab *et al.*

Claim 1 is rejected as allegedly anticipated under 35 U.S.C. §102(b) by Charlab *et al.* (*Proc. Natl. Acad. Sci. USA,* 96:15155-15160, 1999). Applicants respectfully traverse this rejection. However, solely to advance prosecution in this case, claim 1 is canceled herein, rendering this rejection of claim 1 moot.

Sousa *et al.*

Claims 1 and 23 are rejected as allegedly anticipated under 35 U.S.C. §102(b) by Sousa *et al.* (*Mem. Inst. Oswaldo Cruz,* 96:997-999, 2001). Applicants respectfully traverse this rejection. However, as discussed above, claim 1 is canceled herein, rendering this rejection of claim 1 moot. Claim 23 is amended to depend from claim 2. As Sousa *et al* does not disclose a pharmaceutical composition comprising SEQ ID NO: 15 or variants thereof, claim 23 is not anticipated by Sousa *et al.*

In light of the above arguments and amendments, Applicants respectfully request that the rejection of claims 1 and 23 under 35 U.S.C. §102(b) be withdrawn.

*Request for Examiner Interview*

Applicants believe the application is in condition for allowance and such action is requested. Examiner Baskar is formally requested to contact the undersigned prior to issuance of an allowance in order to arrange a telephonic interview to discuss rejoinder of withdrawn claims. If an additional rejection is asserted, or if the present rejection is maintained, Examiner Baskar is also formally requested to contact the undersigned in order to arrange a telephonic interview prior to issuance of the next Office action. It is believed that a brief discussion of the merits of the present application may expedite prosecution. This request is being submitted under MPEP §713.01, which indicates that an interview can be arranged in advance by a written request.

**Conclusion**

Based on the foregoing amendments and arguments, the claims are in condition for allowance and notification to this effect is requested. If for any reason the Examiner believes that a telephone conference would expedite allowance of the claims, please telephone the undersigned at the number listed below.

Respectfully submitted,

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